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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,687	11/15/2000	Stanley J. Watowich	122144-1008	5312

7590

03/09/2004

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EXAMINER
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LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/713,687

Applicant(s)

WATOWICH ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, 50-58 and 75-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 50-58 and 75-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/10/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

Claims 5-6, 50-58 and 75-80 are pending.

***RCE***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the previous allowance has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/31/2002 has been entered. An Office Action of RCE follows:

***New Matter Objection***

***(A)***

The amendment of paper No. 10, filed on 08/29/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows:

Claims 56-59 are all new matters.

Applicant is required to cancel the new matter in the reply to this Office Action.

***(B)***

The amendment of paper No. 12, filed on 02/10/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows:

In claim 5, lines 7-8: "after which no additional purification step is required."

Applicant is required to cancel the new matter in the reply to this Office Action.

***(C)***

The amendment of paper No. 16, filed on 07/11/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows:

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Claim 55, lines 2-3, "wherein the said tRNA molecule is selected from the group consisting of hepatitis C virus genome and flavivirus genome"

Applicant is required to cancel the new matter in the reply to this Office Action.

**(E)**

The amendment of paper No. 18, filed on 01/05/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows:

In claim 75, lines 5-6: " after which no additional purification step is required."

Claim 80 is a new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

***New matter Rejection***

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the amendment of claim 5, lines 7-8 and amendment of claim 75, lines 5-6, the recitation of " after which no additional purification step is required." is a new matter since it is not disclosed in specification that is original filed.

Claim 55 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the amendment of Claim 55, lines 2-3, the amendment "wherein the said tRNA molecule is selected from the group consisting of hepatitis C virus

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genome and flavivirus genome” is a new matter because it is not disclosed in specification as it was original filed.

Claims 56-59 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the specification does not have a possession for having a product of a viral pseudo-nucleocapsid consisting of at least the first 124 amino acids of hepatitis C capsid protein and tRNA is formed in an inset cell host, Sf-9 insect cell host, mammalian cell host and a yeast cell host as the invention was filed. Because there is no any disclosure in the specification that teaches a virus pseudo-nucleocapsid comprising at least the first 124 amino acids of hepatitis C capsid protein and tRNA is formed in an inset cell host, Sf-9 insect cell host, mammalian cell host and a yeast cell host.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 6 is indefinite in that it fails to be consistent with what it is claimed in the independent claim 5. Therefore, claim 6 is rejected.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 75, 76, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasui et al. (J. Virol. 1998, Vol. 72, No. 7, pp. 6048-6055) in light of teaching by Darnell et al. Chapter 3 in Molecular Cell Biology edited by Darnell et al. published by Scientific American Books, Inc. 1990, pp. 87-88).

7. Yasui et al. teach a method for generating a recombinant HCV core protein particle by using a recombinant vaccinia virus that comprises a cDNA encoding the full length of HCV capsid (core) protein to infect mammalian cells (RK13) or HPB-Ma cells and express the HCV core protein as a viral like particle (See pages 6048-6049, Fig. 1, , Fig. 2, Fig. 4 and Fig. 5). While Yasui et al. do not particularly teach that a tRNA molecule is involved in the process of VLP synthesis and formation; the tRNA is inherently participated in the whole process in light of the teaching by Darnell et al. Darnell et al. teach that the design and function of the protein-synthesizing apparatus is similar in all cells. Three kinds of RNA molecules perform different but cooperative roles. Massager RNA (mRNA) encodes the genetic information copied from DNA in the form of a sequence of base that specifies a sequence of amino acids. Transfer RNA (tRNA) is the key to the code; the amino acids specified by the base sequence of a mRNA molecule is carried to and deposited at the growing end of a polypeptide chain by specific tRNA molecules (See section of protein Synthesis: the three Roles of RNA in pages 87-88). Moreover, the recombinant polypeptide of HCV core protein taught by Yasui et al. is a full length recombinant protein, it inherently comprises at least the first 124 amino acids of a HCV capsid protein. Hence, the claimed invention is anticipated by the cited reference.

### ***Conclusion***

While claims 50, 51, 77, 78 and 79 are free of rejection, they are not in the condition for allowance because they depend on rejected claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 517-272-0904. The examiner can normally be reached on 7:00 to 4:00.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 517-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

03/04/2004

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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3/8/04